

## **REMARKS**

This Amendment is responsive to the Office Action of July 18, 2002. Claims 1, 9, 16, 25, 29 and 32 have been amended. Thus, Claims 1-34 are pending in this case. Reexamination and reconsideration are respectfully requested.

### **CLAIM REJECTIONS – CLAIMS 1-34 – § 102(e)**

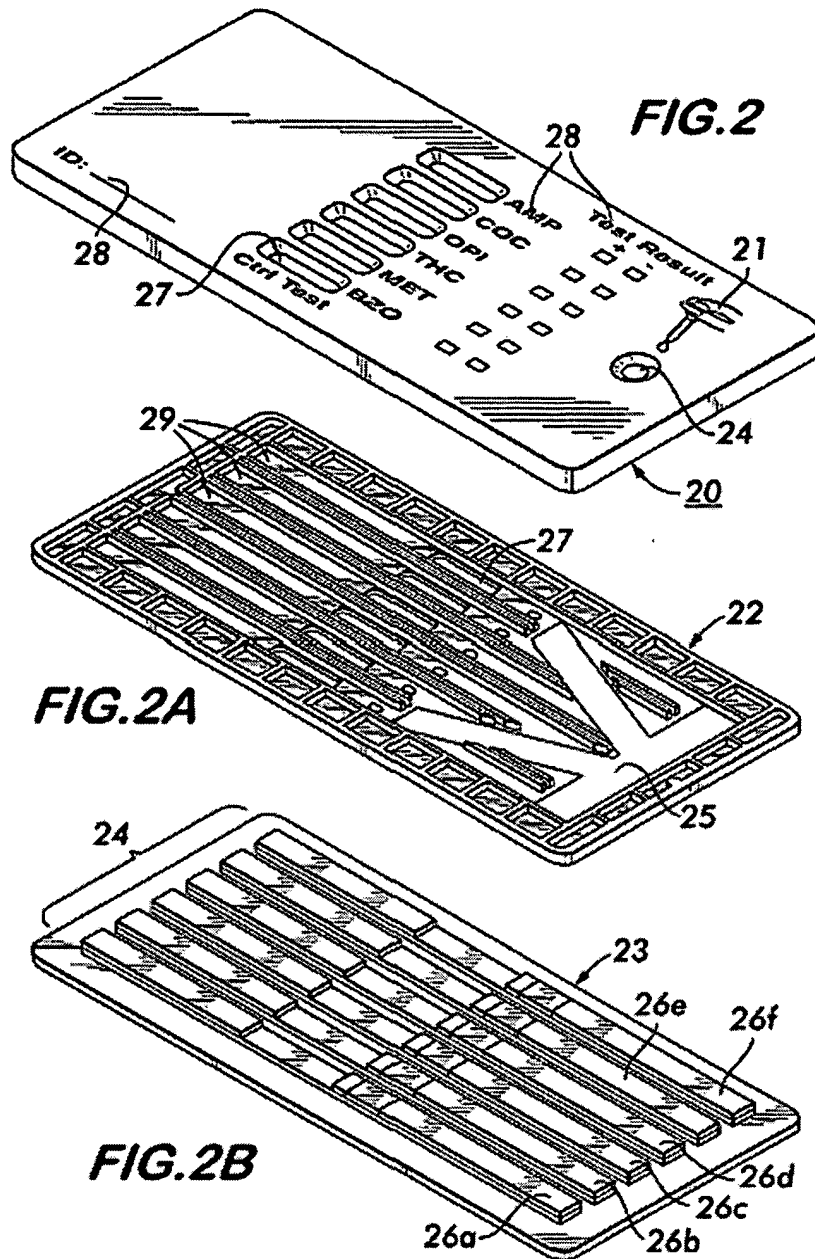
In the Office Action, Claims 1-34 were rejected under 35 U.S.C. § 102(e) as being anticipated by Lu et al (US 6,203,757). Applicant respectfully traverses this rejection. Of the rejected claims, Claims 1, 9, 16, 25, 29 and 32 are independent.

Claim 1 is directed to a lateral flow test strip assembly for testing urine. Unlike a conventional immunoassay test strip, the claimed invention is directed to a test assembly that mimics the lateral flow, wicking action of immunoassays without actually using an immunoassay. The lateral flow is provided by a reagent-free absorbent strip that directs the liquid to a contact detection pad.

As described in the specification, this contact detection pad provides a detectable response simply upon contact with the liquid sample if a certain substance is present (11:18-19). The contact detection is distinguished from an immunoassay in that it does not include antigens or antibodies, it does not include predisposed chemicals designed to be carried along the pad, and it does not provide for wicking as would an immunoassay (11:3-5, 13-17). Examples of contact detection pad include, without limitation, pads that test for adulteration, blood, glucose, pH and more (10:22 – 11:2). One of the many advantages of the claimed invention is that the claimed test strip assembly may be incorporated in the same housing that also includes a separate lateral

flow test strip. As an example and not by way of limitation, a test strip assembly according to the invention may be configured to test for adulteration, for example, and be incorporated the in the same housing that also includes a separate immunoassay, for example, that tests for the presence of certain illegal substances.

As shown in Figures 2, 2A and 2B of Lu et al. as provided below, the cited reference is directed to a device that simplifies the deposit of the liquid sample by providing a single port 24 for receiving the liquid sample. A distribution web 25 then absorbs the liquid and spreads it across a plurality of immunoassay test strips 26a-e. Nothing in Lu et al. suggests that the test strips 26a-e are anything other than conventional immunoassays. The primary focus of Lu et al. is to collect the liquid sample at a single place, and then distribute the deposited liquid sample across the test strips. As a result, a plurality of different immunoassay tests may be conducted without requiring the operator to make separate deposits of liquid for each immunoassay strip.



As discussed above, Applicant's contact detection pad is clearly described in the specification as not being an immunoassay. To clarify this distinction, Applicant has amended Claim 1 and each pending independent claim to recite "non-immunoassay." The claimed invention, however, does allow for a wicking action that mimics

immunoassays such that the claimed test strip assembly may be conveniently incorporated into a test device, such as a cassette, that houses other wicking test strip assemblies, e.g., immunoassays.

Applicant has amended each independent claim to recite "non-immunoassay." Therefore, Applicant respectfully submits that each independent claim is allowable over Lu et al. Applicant further submits that the dependent claims are allowable over the cited reference for their dependence on allowable independent Claims 1, 9, 16, 25, 29 and 32, for the further patentable features recited therein, and for any further grounds as may be recognized by the Examiner.


#### **SUMMARY**

Based on the above amendments and accompanying remarks, Applicant respectfully submits that all pending claims are in condition for allowance and respectfully requests a Notice of Allowance. Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on

January 21, 2003

by Angela Williams

  
Signature

January 21, 2003

Respectfully submitted,



Vic Lin

Registration No. 43,754

Myers, Dawes & Andras LLP

19900 MacArthur Boulevard, Suite 1150

Irvine, CA 92612

(949) 223-9600

## **Version With Markings To Show Changes Made**

### **In the Claims:**

The claims have been amended as follows:

1. (Amended) A lateral flow test strip assembly for testing urine, the assembly comprising:

a support;

a non-immunoassay contact urinalysis pad coupled to the support, the contact urinalysis pad comprising an absorbent carrier and a reagent composition adapted to detect for one or more substances upon contact;

a reagent-free absorbent strip coupled to the support, the absorbent strip being in fluid communication with the contact urinalysis pad, the absorbent strip adapted to receive the urine and to communicate the urine to the contact urinalysis pad.

9. (Amended) A chemical test assembly adapted to test for the presence of multiple substances in a liquid sample, the assembly comprising:

a first backing;

a first non-immunoassay contact detection pad coupled to the first backing, the first contact detection pad including a first absorbent carrier and a first reagent composition adapted to detect a first substance;

a first absorbent strip coupled to the first backing, the first absorbent strip in communication with the first contact detection pad;

a second absorbent strip in fluid communication with the first absorbent strip;  
a second non-immunoassay contact detection pad in communication with the  
second absorbent strip; and  
a second backing disposed between the second contact detection pad and the  
first absorbent strip.

16. (Amended) A chemical testing device comprising:

a housing;

a non-immunoassay contact detection pad including a reagent composition  
adapted to detect one or more specific substances upon contact; and  
a reagent-free absorbent strip in communication with the contact detection pad.

25. (Amended) A lateral flow assembly for detecting a substance in a liquid  
sample, the assembly comprising:

a support;

a non-immunoassay contact detection pad coupled to the support, the contact  
detection pad comprising an absorbent carrier and a reagent composition  
adapted to detect for one or more substances upon contact; and

a reagent-free absorbent strip coupled to the support, the absorbent strip being in  
fluid communication with the contact detection pad, the absorbent strip  
adapted to receive the liquid sample and to communicate the liquid  
sample to the contact detection pad.

29. (Amended) A method for performing urinalysis, comprising:

receiving the urine with a reagent-free absorbent strip;

providing an non-immunoassay urinalysis pad with a reagent composition

dispersed therein and adapted to detect a target substance upon contact;

laterally flowing the urine to the urinalysis pad with the absorbent strip; and

providing a detectable response as a result of detection of the target substance.

32. (Amended) A method for manufacturing a combined drug testing and adulteration testing device, the method comprising:

providing a housing;

disposing a drug test strip in the housing;

disposing in the housing a reagent-free absorbent strip in communication with a

non-immunoassay contact detection pad; and

preventing fluid communication between the drug test strip, on the one hand, and

the absorbent strip and the contact detection pad, on the other hand.